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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,834	02/13/2002	Johannes Booij	246152015300	5546

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EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/937,834	BOOIJ ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See memo.*

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *10,12-14,16-20,27-29,31,32,34-37,39-44 and 46-54*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Mark L. Berch
Primary Examiner
Art Unit: 1624

DETAILED ACTION

The amendment filed 8/27/2004 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: The proposed amendment raises new issues that would require further consideration and/or search. Also, the proposed amendment presents additional claims 55-57 without canceling a corresponding number of finally rejected claims.

The phrase "wherein said agglomerate is substantially free from non-agglomerate crystals in the needle form and is other than the rosette-like crystalline form of potassium clavulanate." Presents several problems:

A. It is unclear whether the "in the needle form" is a) part of what is claimed or b) part of what is excluded. That is, is it "wherein said agglomerate is ... in the needle form and is other than..." or is the excluded choice "non-agglomerate crystals in the needle form"? It could be read either way. Applicants point to page 5, lines 18-20 for descriptive support for what is excluded, and that wording makes no mention of needles, which is consistent with a), and a) avoids the issue B below, but on the other hand, the remarks seem to indicate that applicants actually intend b).

B. If b) is intended, the "non-agglomerate crystals in the needle form" is self-contradictory because, as was noted in the First Action on the Merits, all crystals are by their very nature agglomerates.

C. It is unclear what "substantially free" requires in terms of percentage. Page 5 says "for instance", 0-10%. That makes it clear that 0-10% is "substantially free" but leaves up

in the air whether 12% or 15% or 20% is also "substantially free". The examiner must also note that 10% itself already seems rather high to be considered insubstantial.

D. The claim has the new concept of "non-agglomerate crystals". It is not at all clear what particle size is the boundary between "non-agglomerate" and "agglomerate". If a particle is 1 μm size, is it "non-agglomerate" or "agglomerate"? 0.4 μm? 0.1μm? 0.04 μm? 0.01 μm? 0.001 μm? Presumably, at some point the particle is small enough to fall into the "non-agglomerate" category, but where is that point?

Also, the new "pharmaceutically acceptable" claim language inserted into e.g. claim 10 is of unknown purpose. There are only a few alkali metals, and they are all pharmaceutically acceptable, so what role does this claim language play?

The traverse of the enablement requirement is unpersuasive. It is agreed that experimentation, so long as it is not "undue" is permitted, but as noted, crystallization is very sensitive to the size of what is being crystallized, and, as noted, elements Li and Cs are of very different size, and cannot reasonably be expected to have the same behavior as K. There are many examples of K and Cs salts e.g. the azides, which form different crystalline forms. Likewise for K and Li salts, e.g. oxalate.

The traverse of the description issue is unpersuasive. Page 5 clearly states, "The present invention provides agglomerates in crystalline form comprising one or more β-lactam compounds having at least one β-lactam compound of a high water affinity, and optionally contain one or more..." This explicitly states that applicants are claiming

agglomerates of a "β-lactam compound of a high water affinity" --- not agglomerates of any β-lactam, but agglomerates of a β-lactam compound of a high water affinity. A crystalline agglomerate of a β-lactam compound having a low water affinity is not covered by the specification, but would be by the claims. Some crystalline forms have high water affinity, some do not.

As for '069, why would waisted plates be excluded? As for '352, applicants do not explain why the product must be needles. As for "069 and '352 (i.e. paragraph bridging pages 10-11 of remarks), this is very vague, using terms like "relatively large" and "small", with no clear lines set forth. As for '861, applicants present no reasoning why these would have to be rosettes. As for WO 97/33564, the reference still says agglomerate, and claim 37 does not bar other ingredients. WO 98/21212 would be overcome by the limitation of only alkali metal salts.

The proposed claim language for claim 31 would have resolved that matter.

The request for the withdrawal of the finality is denied. MPEP 706.07(b) refers to the first action Final not being proper "... where that application contains material which was presented in the earlier application after final rejection .... but was denied entry because..." But that is not what happened, because there was no such material. The Advisory Action identified the material which raised a new issue as the indefiniteness of the "obtained without stirring" claim language which applicants sought to insert into claims 30 and 45. When applicants submitted fresh claims with the RCE, that claim language was not present. Specifically, claims 30 and 45 were canceled, and the "obtained without stirring" claim language was not present in any other claim.

Therefore, the claims as submitted with the RCE did not contain any material that was presented earlier but was denied entry because it raised a new issue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571)272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Berch
Primary Examiner
Art Unit 1624

9/2/04